DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

PURITAN MEDICAL PRODUCTS LLC
MEHDI KARAMCHI
VICE PRESIDENT OF SCIENTIFIC AFFAIRS
31 SCHOOL STREET
P.O. BOX 149
GUILFORD ME 04443

January 9, 2015

Re: K142366
Trade/Device Name: Puritan Optitranz Liquid Stuart Collection And Transport System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: I
Product Code: JSM, LIO, JTW
Dated: December 3, 2014
Received: December 11, 2014

Dear Mr. Karamchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142366

Device Name
Puritan OptiTranz Liquid Stuart Collection and Transport System

Indications for Use *(Describe)*
Puritan OptiTranz Liquid Stuart Collection and Transport System is intended for use in the collection and transport of clinical specimen containing aerobic and fastidious bacteria from patient to the laboratory for bacteriological examination and culture.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Puritan® OptiTranz™ Liquid Stuart Medium

5.1 Sponsor

Puritan Medical Products LLC

31 School St., Guilford, ME

04443

Contact: Mehdi Karamchi

Telephone Number: 207-876-3311

Date: August 19, 2014

5.2 Device Name

Classification Name: Microbiological Specimen Collection and Transport Device

Common Name: Specimen Collection and Transport System

Proprietary Name: Puritan OptiTranz Liquid Stuart Collection and Transport System

5.3 Regulatory Information

A. Regulatory Section: 21 CFR 866.2390

B. Classification: Class I

C. Product Code: JSM, LIO, JTW

D. Panel: Microbiology

5.4 Predicate Device

BD CultureSwab™ Collection and Transport System manufactured by Copan Diagnostics Inc. of Italy

510K Number: K946283

5.5 Device Description

Puritan OptiTranz Collection and Transport System is comprised of a sterile peel pouch containing a rayon or flock tipped swab applicator for collecting specimen and a polypropylene vial containing 1 ml of Stuart liquid medium.

Puritan OptiTranz Liquid Stuart Medium is a nonnutritive balanced salt solution containing phosphates to provide buffering capability and calcium chloride to provide essential ions that help maintain osmotic balance. Mercaptoacetic acid provides a reduced environment. It is recommended for maintaining the viability of aerobic and fastidious bacteria during the transport to the laboratory.

For prescription use only.

5.6 Intended Use

Puritan OptiTranz Liquid Stuart Collection and Transport System is intended for use in the collection and transport of clinical specimen containing aerobic and fastidious bacteria from patient to the laboratory for bacteriological examination and culture.

5.7 Indication(s) For Use

Purtian OptiTranz Liquid Stuart Collection and Transport System is intended for use in the collection and transport of clinical specimen containing aerobic and fastidious bacteria from patient to the laboratory for bacteriological examination and culture.

5.8. Substantial Equivalence statement

Puritan OptiTranz is similar in design, manufacturing and intended usage to the predicate device. Both Puritan and predicate device are single-use devices intended for collection and transport of clinical specimens containing aerobes and fastidious bacteria.

Puritan Versus Predicate Similarities		
Item	Puritan OptiTranz Liquid Stuart Collection and Transport System K142366	BD CultureSwab™ Collection and Transport K946283
Intended USE	Puritan OptiTranz Liquid Stuart Collection and Transport System is intended for use in the collection and transport of clinical specimen containing aerobic and fastidious bacteria from patient to the laboratory for bacteriological examination and culture.	Copan Venturi Transystem Liquid Stuarts Medium products (141C, 143C & 139C) are sterile ready-to-use systems intended for the safe collection, transport, and preservation of clinical specimens for bacteriological examination. Product 141C (plastic applicator) is intended for collecting samples from the throat, vagina, or from wounds. Product 143C (aluminum applicator) is intended for collection of specimens from small or less accessible areas such as eye, ear, nose, throat,

		urogenital tract and for pediatric use. Product 139C (two plastic applicators) is used for throat, vaginal, or wound sampling. The double swab permits use of the second sample in the laboratory of gram stain analysis or as a backup for verification of initial culture.
Single-use Device	Yes	Same
Medium Formulation	Sodium Glycerophosphate Calcium Chloride Mercaptoacetic acid	Same
pH	7.3 ± 0.2	Same
Storage Temperature	2-25°C (refrigerated and room temperature)	5-25°C (refrigerated and room temperature)
Container	Plastic round bottom tube	Same
Product Configuration	Medium in tubes, Plug & polyurethane foam System including medium and swab in peel pouch option.	Same
Swab Shaft	Plastic	Same

Item	Test Device	Predicate
Swab Tip	Rayon or flock tipped swab	Rayon tipped swab
Shelf Life	18 months	Same

5.9 Recovery Testing

To determine the ability of the Puritan OptiTranz to maintain viability of different strains of aerobes and fastidious bacteria, known inoculum of ATCC type culture and clinically significant microorganisms were inoculated into the Puritan OptiTranz and compared to the predicate device following Clinical and Laboratory Standards Institute (CLSI), M40-A2 guidelines. No significant differences in recovery were detected between samples obtained from Puritan OptiTranz vs. predicate device.

5.10 Stability Testing

Stability tests were performed on Puritan OptiTranz products to verify the ability of the aged products to maintain microbial recovery up to the expiry date.

5.11 pH Stability

The pH of the test device was measured at predetermined time intervals up to 18 month after manufacturing date. The test was performed using calibrated pH meter with random samples from three different lots of Puritan OptiTranz liquid Stuart medium. All samples tested were found to maintain pH within the specified range.

5.12 Cytotoxicity

Cytotoxicity test was conducted to evaluate Glue, shaft and the rayon or flock tipped swabs for potential cytotoxicity effect following ISO Elution Method-1X MEM Extract. No evidence of cytotoxicity was detected.

5.13 Sterilization

Puritan OptiTranz Collection and Transport Systems are sterilized by gamma irradiation and validated following ANSI/AAMI/ISO 11137:2006, Sterilization of health care products Radiation guidelines.